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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/824,851	04/02/2001	Sharat Singh	0225-0033.26	1092

22918 7590 01/30/2002

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EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 01/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/824,851

Applicant(s)

Singh et al.

Examiner

Joyce Tung

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5-7 of copending Application No. 09/824,905, claims 1-9 of copending Application No.09/825,245, claims 1-4 of copending Application No. 09/824,861 and claims 1-5 of copending Application No. 09/825,246. Although the conflicting claims are not identical, they are not patentably distinct from each other because the limitations of the instant claims 1-4 of Application No. 09/824851 are drawn to a kit comprising a set of electrophoretic tag probes which has the same feature as the set of the electrophoretic tag as claimed in claims 1-3 and 5-7 of copending Application No. 09/824,905 except that the component T_j of the probe of copending Application No. 09/824,905

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is an oligonucleotide target-binding moiety having a sequence of nucleotide U_i connected by intersubunit linkages $B_{i,i+1}$. The component T_j of the set of e-tag probe of instant invention encompasses the component T_j of copending Application. The component N of copending Application 09/824,905 is a nucleotide joined to U_i . Functionally and structurally, the component N of copending Application 09/824,905 is same as the component L of the probe which is a linking group connected to the component T_j and nuclease cleavable. The electrophoretic tag probe of instant claims 1-4 of copending Application No. 09/824,851 also has the same feature as the electrophoretic tag probe of the composition claims 1-9 of copending Application No.09/825,245 except that the set of the electrophoretic tag probe of copending Application No.09/825,245 is in the composition and the features of the set of e-tag probe of copending Application No.09/825,245 are the same as the e-tag probe of copending Application 09/824,905 as discussed above. In addition, the electrophoretic tag probe of instant claims 1-4 also has the same feature as the electrophoretic tag probe of claims 1-4 of copending Application No. 09/824,861 except that the set of electrophoretic tag probe is in a composition. Further, the electrophoretic tag probe of instant claims 1-4 has the same feature as the electrophoretic tag probe of claims 1-5 of copending Application No. 09/825,246 except that the claims of copending Application No. 09/825,246 are drawn to a set of electrophoretic tag probes with the feature discussed in the e-tag probe of copending Application 09/824,905 above. Thus, an ordinary skill in the art at the time of the instant invention would have been motivated to construct the kit as claimed including the set of electrophoretic tag probe or the set of

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electrophoretic tag probes from the composition since these electrophoretic tag probes have the same structural features. Constructing a kit was well known in the art at the time of the instant invention for performing a method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claims 1-4 are vague and indefinite because it is unclear what is the number of the subscript of T_j in claim 1-4 and what is the "J member".
- b. Claims 1-4 are vague and indefinite because it is unclear what is the antecedent basis for the language "the reacted target sequences" in claim 1 (b)(ii).
- c. Claim 4 is vague and indefinite because the language "a particle" has not antecedent basis.

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d. Claims 1-4 are vague and indefinite because it is unclear what is the definition of the phrase "a mobility modifier having a charge/mass". Since every molecule has charges and mass, every molecule has the mobility property. It is suggested to clarify uncertainty.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Grossman et al.
(5,470,705)

Grossman et al. disclose a probe comprising the feature of the e-tag probe as claimed in claim 1. The probe of Grossman et al. is captured (See column 20, lines 47-49). Thus it is inherent that there is a capture agent bound to the probe. The probe includes a binding polymer, a polymer chain which imparts to that probe, a distinctive ratio of charge/translational frictional drag and a reporter attached to the binding polymer (See column 20, lines 52-57). The probe is also cleavable with nuclease at the 5' end subunits from the probe and the probe releases a labeled probe composed of base, reporter and polymer chain (See column 19, lines 62-67 to column 20, lines 1-25). The binding polymer is an oligonucleotide including at least 10-20 bases allowing hybridization to the target polynucleotide (See column 6, lines 66-67 and column 7, lines 1-10). Other binding polymers are analogs of polynucleotides, such as deoxynucleotides

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with thiophosphodiester linkage (See column 7, lines 11-19). The polymer chain has a ratio of charge/translational frictional drag which is evidenced by a distinctive electrophoretic mobility in a non-sieving matrix (See column 7, lines 50-64). The label refers to a fluorophore or chromophore (See column 6, lines 39-44). The feature of Grossman et al.'s probe anticipate the features of the claimed e-tag probe.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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8. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grossman et al. (5,470,705), as applied to claim 1 above, and further in view of Babon et al. (5,851,770).

The teachings of Grossman et al. are set forth in section 6 above. Grossman et al. do not disclose that the probe contains a capture ligand as indicated in claims 2-3.

Babon et al. disclose a method for detecting one or more mismatches between a first and second nucleic acid in which the heteroduplex formed between the first and second nucleic acid sequence is biotinylated and captured by binding to streptavidin-magnetic beads (See column 7, lines 53-66). The capture ligand and capture agent includes antigen/antibody or DNA binding protein and its DNA binding site (See column 18, lines 13-24). Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time of the instant invention to modify the probe of Grossman et al. wherein the capture ligand/agent are attached to the oligonucleotide probe as taught by Babon et al.. The ordinary artisan would have been motivated to make this invention because directly capturing the probe to a solid support is easy to wash away the unbound probe, which increases the accuracy of the method instead of capturing the probe through the immobilized target sequence as disclosed by Grossman et al.. It was well known at time of the instant invention.

9. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1656 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

January 25, 2002

A handwritten signature in black ink, appearing to read "E. Campbell". The signature is fluid and cursive, with the first letter "E" being large and stylized.

**EGGERTON A. CAMPBELL
PRIMARY EXAMINER**